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PATENT

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RPR

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Russell Mumper
Michael Jay

Serial No.: Unknown

Filed: Concurrently Herewith

For: pH-SENSITIVE MUCOADHESIVE FILM-
FORMING GELS AND WAX-FILM
COMPOSITES SUITABLE FOR
TOPICAL AND MUCOSAL DELIVERY
OF MOLECULES

Group Art Unit: 1616

Examiner: Dewitty, Robert

Atty. Dkt. No.: NANO:002USD1

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Commissioner:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to

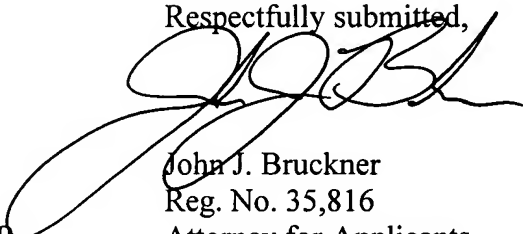
be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Account No.: 50-1212/08010548/NANO:002USD1/JJB.

This application is a divisional application of Serial No. 09/748,133, filed December 27, 2000, and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/748,133.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Date: February 7, 2002

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (PTO-1449)		ATTY. DOCKET NO. NANO:002USD1		SERIAL NO. Unknown			
		APPLICANT Russell MUMPER, et al.					
		FILING DATE Concurrently Herewith		GROUP 1616			
U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	FILING DATE		
FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
Aspden, T.J., Adler, J., Davis, S.S., Skaugrud, O., Illum, L. Chitosan as a nasal delivery system: evaluation of the effect of chitosan on mucociliary clearance rate in the frog palate model. <i>Int. J. Pharm.</i> 122:69-78, 1995.							
Bayley, D., Temple, C., Clay, V., Steward, A., Lowther, N. The transmucosal absorption of recombinant human interferon-alpha B/D hybrid in the rat and rabbit. <i>J. Pharm. Pharmacol.</i> 47:721-724, 1995.							
Berthold, A., Cremer, K., Kreuter, J. Preparation and characterization of chitosan microspheres as drug carriers for prednisolone sodium phosphate as a model for anti-inflammatory drugs. <i>J. Cont. Rel.</i> 39:17-25, 1996.							
Bhatt, L.D., Johnston, T.P. In vitro release and permeation of oxytocin from a mucoadhesive buccal patch. <i>Pharm. Dev. Technol.</i> 1:357-364, 1996.							
Bhatt, L.C., Johnston, T.P. Transmucosal devliery of oxytocin to rabbits using a mucoadhesive buccal patch. <i>Pharm. Dev. Technol.</i> 2:265-274, 1997.							
✓ Bodde, H.E., de Vries, M.E., Junginger, H.E. Mucoadhesive polymers for the buccal delivery of peptides, structure-adhesiveness relationships. <i>J. Cont. Rel.</i> 13:225-231, 1990.							
✓ Duchene, D., Touchard, F., Peppas, N.A. Pharmaceutical and medical aspects of bioadhesive systems for drug administration. <i>Drug Devol. Ind. Pharm.</i> 14:283-318, 1988.							
Goto, S., Kawata, M., Suzuki, T., Kim, N.S., Ito, C. Preparation and evaluation of Eudragit gels. I: Eudragit organogels containing drugs as rectal sustained-release preparations. <i>J Pharm Sci.</i> 80:958-961, 1991.							
Hardy, E., Jimenez, A.L., de Padue, K.S., Zaneveld, L.J. Women's preferences for vaginal antimicrobial contraceptives. III. Choice of a formulation, applicator, and packaging. <i>Contraception.</i> 58:245-249, 1998a.							
Hardy, E., de Padu, K.S., Osis, M.J., Jimenez, A.L., Zaneveld, L.J. Women's preferences for vaginal antimicrobial contraceptives. IV. Attributes of a formulation that would protect from STD/AIDS. <i>Contraception,</i> 58:251-255, 1998b.							
EXAMINER				DATE CONSIDERED			

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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
Harris, D., Robinson, J.R. Bioadhesive polymers in peptide and drug delivery. <i>Biomaterials</i> , 11:652-558, 1990.							
Henriksen, I., Vagen, S.R., Sande, S.A., Smistad, G., Karlsen, J. Interactions between liposomes and chitosan II: effect of selected parameters on aggregation and leakage. <i>Int. J. Pharm.</i> 146:193-204, 1997.							
Illum, L., Farraj, N.F., Davis, S.S. Chitosan as a novel nasal delivery system for peptide drugs. <i>Pharm. Res.</i> 11:1186-1189, 1994.							
Imai, T., Shiraishi, S., Saito, H., Otagiri, M. Interaction of indomethacin with low molecular weight chitosan, and improvements of some pharmaceutical properties of indomethacin by low molecular weight chitosans. <i>Int. J. Pharm.</i> 67:11-20, 1991.							
Kawata, M., Suzuki, T., Kim, N.S., Ito, T., Kurita, A., Miyagoe, Y., Goto, S. Preparation and evaluation of Eudragit gels. II: In vitro release of salicylic acid, sodium salicylate, and ketoprofen from Eudragit L and S organogels. <i>J Pharm Sci.</i> 80:1072-1074, 1991.							
Khan, M.Z., Prebeg, Z., Kurjakovic, N. A pH-dependent colon targeted oral drug delivery system using methacrylic acid copolymers. I. Manipulation of drug release using Eudragit L100-55 and Eudragit S100 combinations. <i>J Controlled Release.</i> 58:215-22, 1999.							
Kim, N.S., Umejima, H., Ito, T., Uchida, T., Goto, S. Preparation and evaluation of Eudragit gels. V. Rectal gel preparations for sustained release and avoidance of first-pass metabolism of lidocaine. <i>Chem Pharm Bull.</i> 40:2800-2804, 1992a.							
Kim, N.S., Ito, T., Kawata, M., Uchida, T., Goto, S. Preparation and evaluation of Eudragit gels. IV: Rectal gel preparations for sustained release and avoidance of first-pass metabolism of propentofylline. <i>J Pharm Sci.</i> 81:904-907, 1992b.							
Kim, N.S., Kawata, M., Uchida, T., Goto, S. Preparation and evaluation of Eudragit gels. III: Rectal gel preparations for sustained release of pentoxifylline. <i>J Pharm Sci.</i> 81:537-40, 1992.							
Lehr, C.M., Bouwstra, J.A., Schacht, E., Junginger, H.E. In vitro evaluation of mucoadhesive properties of chitosan and some other natural polymers. <i>Int. J. Pharm.</i> 78:43-48, 1992.							
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	MacLaughlin, F.C, Mumper, R.J., Wang, J., Tagliaferri, J.M., and Rolland, A.P. Chitosan and depolymerized chitosan oligomers as condensing carriers for in-vivo plasmid delivery. <i>J. Controlled Rel.</i> 56:259-272, 1998.						
	Meshali, M.M., Gabr, K.E. Effect of interpolymer complex formation of chitosan with pectin or acacia on the release behavior of chlorpromazine HCl. <i>Int. J. Pharm.</i> 89:177-181, 1993.						
	Sayani, A.P., Chun, I.K., Chien, Y.W. Transmucosal delivery of leucine enkephalin: stabilization in rabbit enzyme extracts and enhancement of permeation through mucosae. <i>J. Pharm. Sci.</i> 82:1179-1185, 1993.						
	Schipper, N.G.M., Varum, K.M., Artursson, P. Chitosans as absorption enhancers for poorly absorbable drugs. I: influence of molecular weight and degree of acetylation on drug transport across human intestinal epithelial (Caco-2) cells. <i>Pharm. Res.</i> 13:1686-1692, 1996.						
	Scott, R.C., Besag, F.M.C., Neville, B.G.R. Buccal midazolam and rectal diazepam for treatment of prolonged seizures in childhood and adolescence: a randomized trial. <i>The Lancet.</i> 353:623-626, 1999.						
	Shiraishi, S., Imai, T., Otagiri, M. Controlled release of indomethacin by chitosan-polyelectrolyte complex: optimization and in vivo/in vitro evaluation. <i>J. Cont. Rel.</i> 25:217-225, 1993.						
	Takayama, K., Hirata, M., Machida, Y., Masada, T., Sannan, T., Nagai, T. Effect of interpolymer complex formation on bioadhesive property and drug release phenomenon of compressed tablet consisting of chitosan and sodium hyaluronate. <i>Chem. Pharm. Bull.</i> , 38:1993-1997, 1990.x						
	Takeuchi, H., Yamamoto, H., Niwa, T., Hino, T., Kawashima, Y. Enteral absorption of insulin in rats from mucoadhesive chitosan-coated liposomes. <i>Pharm. Res.</i> 13:896-901, 1996.						
	Umejima, H., Kim, N.S., Ito, T., Uchida, T., Goto, S. Preparation and evaluation of Eudragit gels. VI: In vivo evaluation of Eudragit rectal hydrogel and xerogel containing salicylamide. <i>J Pharm Sci.</i> 82:195-9, 1993.						
	Wong, C.F., Yuen, K.H., Peh, K.K. Formulation and evaluation of controlled release Eudragit buccal patches. <i>Int. J. Pharmaceutics.</i> 178:11-22, 1999.						
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